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Hikma Seeks Rehearing In Vascepa Skinny-Label Case

Claims Panel Decision To Reopen Case Contradicts Precedent And Will Chill Competition

by David Wallace

Hikma has asked the US Court of Appeals for the Federal Circuit for a full court rehearing of a panel decision that earlier this year reopened a dispute with Amarin over a skinny-label generic version of Vascepa.

The full US Court of Appeals for the Federal Circuit should rehear a panel decision from earlier this year that reopened a long running dispute with Amarin over a skinny-label generic version of Vascepa (icosapent ethyl), *Hikma* has urged in a filing with the court.

The case revolves around a claim of induced infringement by Hikma's generic of patent-protected indications of Vascepa, even though Hikma had followed the "section viii" statutory framework and fully carved out Amarin's patented use for reducing cardiovascular risk.

In June, the appeals court reversed a Delaware district court's January 2022 decision to dismiss the case, finding that Amarin's allegations against Hikma plausibly stated a claim for induced infringement and highlighting that it had reviewed the allegations of inducement "as a whole, not piecemeal" (*see sidebar for full details*).

But in its request for an "en banc" rehearing of the June decision, Hikma said the appeals court ruling "contradicts longstanding precedent that requires active steps by the defendant encouraging infringement" and "nullifies labeling carve-outs under section viii and will

'Totality, Not Piecemeal': US Federal Circuit Revives Hikma Vascepa Skinny-Label Suit

severely harm generic competition absent rehearing."

"The panel held that Hikma's description of its generic drug as a 'generic version' of a branded drug, along with references to annual sales of the branded drug, was sufficient to plead induced infringement of a patented method that Hikma undisputedly carved out of its generic product label," the generics firm pointed out, in a move that "conflicts with this court's precedent on induced infringement and eviscerates a statutory mechanism that congress enacted to expedite access to generic drugs."

By Dean Rudge

26 Jun 2024

Reading Hikma's press releases and other public documents made it "at least plausible" that a physician would look to prescribe Hikma's generic Vascepa product for any of its indications, including the highly-valued, patent-protected cardiovascular indication, the US Federal Circuit has decided, reopening a lawsuit against the generics firm.

Read the full article here

"Left uncorrected," Hikma warned, "the decision will deter generic competition and expand the risk of inducement liability even beyond the pharmaceutical industry."

Specter Of GSK-Teva Case Looms

Noting that the appeals court had previously been "split sharply over whether to rehear its decision in *GlaxoSmithKine v Teva*" – separate litigation which ultimately saw GSK triumph in an induced-infringement battle over its Coreg (carvedilol) brand (*see sidebar*) – Hikma said "the concurrence made clear, however, that GSK's holding was 'narrow and fact dependent'."

"As proof, the concurrence cited the district court's decision in *this* case, which dismissed Amarin's complain for 'fail[ing] to plead inducement based on Hikma's label or public statements'," Hikma pointed out. "Yet the panel here reversed that decision – drastically expanding GSK's holding."

Moreover, Hikma said, the appeals court's decision to resurrect the Amarin litigation "also conflicts with *GSK*'s holding that 'simply calling a product a generic version is not inducement'."

Industry Impact Weighed As US Supreme Court Refuses Skinny-Label Review

By David Wallace

18 May 2023

Teva has been denied in its attempt to convince the US Supreme Court to re-examine long-running litigation with GSK over skinny-label carve-outs of generic indications. However, the generics firm has vowed to fight

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Emphasizing that the panel had found that Hikma's label was "skinny enough" – in that it "does not, as a matter of law, recommend, encourage, or promote [either] infringing use" – Hikma acknowledged however that plausible inducement had been found because Hikma had referred to its product as a "generic version" of Vascepa and quoted total annual sales for the brand, including patent-protected sales.

on as the case is returned to the district court level, while the wider off-patent industry weighs the impact of the latest decision.

Read the full article here

This was seen by the panel as sufficient to plead "instruction or encouragement to prescribe [Hikma's] drug for *any* of the approved uses of icosapent," including cardiovascular risk reduction, "even though Hikma's statements never *mention* CV risk, much less using icosapent to reduce it."

But the firm argued that "even assuming sales figures could imply *intent* to substitute Hikma's generic product for all Vascepa prescriptions (a stretch), that is not enough because the law requires both 'specific intent *and action* to induce infringement'."

"By allowing inducement claims to proceed without any statement by Hikma encouraging the claimed methods, the decision breaks with longstanding precedent and the inducement statute itself, which limits liability to one who 'actively induces infringement'," Hikma summarized.

It suggested that the court's reasoning "assumes physicians plausibly will read Hikma's press releases, infer they can use Hikma's 'generic version' for all approved uses of Vascepa, and consult Amarin's Vascepa label – not Hikma's label – to determine those uses." But "at most, this is a theory of *passive* inducement. Amarin failed to plead that Hikma *actively* induced physicians to use its product for CV uses."

Allowing Case To Proceed Could Cast Shadow Over Industry

Hikma also drew the court's attention to the potential impact of the case on the wider generics industry, arguing that allowing the litigation to proceed could have a chilling effect on generic competition in general.

"Even before the decision, commentators viewed Amarin's lawsuit as 'a prototype for future litigation' that 'may delay or deter generics from entering the market'," Hikma said. "The decision all but ensures that result."

"Every generic drug, by definition, is a 'generic version' of another product, and market-size discussions are practically unavoidable in communications to investors and the public," Hikma

set out. "If this were enough to plead inducement, *every* skinny label would be litigated."

And even if an Amarin victory was unlikely, Hikma argued, allowing the case to proceed could still make generic competitors think twice. Noting that the panel had dismissed Hikma's concerns as "inflated" because of the "stage of proceedings" on a motion to dismiss, Hikma commented that "true, Amarin's case is weak, and it is unlikely to succeed. But the precedential harm will already be done."

"The threat of protracted litigation through fact and expert discovery is enough to deter generic competition," Hikma warned, observing that "post-launch, skinny-label litigation effectively doubles the cost; Hikma needs to defend a second lawsuit despite winning its Hatch-Waxman case."

"Under the panel decision, no skinny label is safe," Hikma concluded. "Even with slim chances of success, patentees will reflexively file suit if they can get past motions to dismiss based on vague and practically unavoidable statements that an accused product is a 'generic version' competing for a branded product's sales."

"The twin threats of litigation expense and lost-profits damages will deter generic companies from invoking section viii," the firm concluded, "defeating congressional intent to lower drug prices and harming patients and healthcare providers."

'It's Not Going To Be An Easy Market' – Hikma Talks Strategy For US Biosimilars

By David Wallace

14 Aug 2024
During Hikma's first-half results call, the company delved into details of its strategic goals for biosimilars, small-molecule generics, injectables, GLP-1s and more.

Read the full article here

As part of its recent first-half results announcement – which saw the firm report a 10% sales rise to $1.569bn in the first six months of 2024 – Hikma acknowledged the ongoing Vascepa litigation but said that "at this point, the group does not believe sufficient evidence exists to make a reasonable estimate of any potential liability."